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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,226	10/31/2000	Steven E. Walak	BSI-469US	1298

490 7590 07/15/2003

VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER

MATTHEWS, WILLIAM H

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 07/15/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/702,226

Applicant(s)

WALAK, STEVEN E.

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-47 is/are pending in the application.
- 4a) Of the above claim(s) 4-15, 20, 21 and 25-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2, 16-19 and 22-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of claims 17 and 18 recite "said combination" which lacks proper antecedence due to amendments to claim 16.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1,2,16-18, and 22-24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Burmeister et al. WO 95/31945.

Burmeister et al. discloses in figures 1,5,6,8-11,14-16 multiple stent configurations comprising superelastic and plastically deformable sections. As shown in

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Figure 16, superelastic nitinol layer 154 is surrounding by plastically deformable layers 152. Note this pattern continues. Therefore the first section, as claimed, is 154 and the second section begins at adjacent layer 152 and another layer 154 not shown and another layer 152 not shown.

Regarding claims 2 and 23, see lines 3-13 of page 13.

Regarding claims 17-18, see lines 12-18 of page 7.

3. Claims 1,2,16,17,19, and 23 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Chandrasekaran US PN 6,093,157.

Chandrasekaran discloses in Figures 2 and 6 and lines 3-12 of col. 3, lines 1-13 of col. 4, and lines 11-34 of col. 5 an endoluminal device having a first section 52 comprising Nitinol in a plurality of stripes and a second section comprising layers of Nitinol 34 and gold 50. See figures 2-3, line 31 of col. 4 through line 9 of col. 5, and lines 31-49 of col. 7. The gold layer inherently constrains the Nitinol layer when the Nitinol expands due to temperature by virtue of the gold layer surrounding the Nitinol layer.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burmeister et al. WO 95/31945 in view of Alt US PN 6,217,607.

Burmeister et al. meets the limitations of claim 19 as described above but lacks the express disclosure of utilizing gold for the plastically deformable section. Note that Burmeister et al. discloses various alloys comprising gold on page 2, providing strands of platinum or tantalum for radiopacity, and that radiopaque portions or coatings may be included on any parts of the stents (lines 3-18 of page 13). Alt teaches the specific use of gold for a coating on a Nitinol stent to improve radiopacity of the stent.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent disclosed by Burmeister et al. to either substitute gold for the platinum or tantalum strands or to have coated portions of the stent with gold as taught by Alt in order to improve radiopacity of the stent.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1,2,16-19,22-24 have been considered but are not persuasive.

With regard to Heath '570, arguments are now moot.

With regard to Burmeister et al WO 95/31945, Applicant contends that the stent structure does not provide longitudinal stripes present in two sections because the wires are comprised of two alloys. The examiner disagrees because sections of the wires may be interpreted as the first and second sections. As shown in Figure 16, superelastic nitinol layer 154 is surrounded by plastically deformable layers 152. Note

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this pattern continues because of the braiding shown in Figure 15. Therefore the first section, as claimed, is 154 and the second section begins at adjacent layer 152 and another layer 154 not shown, and another layer 152 not shown (for claim 18).

### ***Conclusion***

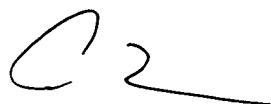
Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

  
WHM

July 13, 2003

  
CORRINE McDERMOTT  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700